

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE BIOGEN '755 PATENT LITIGATION)
) Hon. Claire C. Cecchi
)
) Civil Action No. 10-2734
) (CCC/JBC)
) (consolidated)
)
)
)

**BIOGEN'S MEMORANDUM OF LAW IN OPPOSITION OF BAYER
HEALTHCARE PHARMACEUTICAL INC.'S MOTION TO STRIKE THE
SUPPLEMENTAL REBUTTAL EXPERT REPORT OF PASTOR
COUCEYRO**

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TABLE OF CONTENTS

	Page
INTRODUCTION	1
ARGUMENT	5
I. Biogen Acted Diligently To Obtain Equal Footing with Bayer.....	6
A. Biogen Sought To Conduct the Necessary Experiments Quickly	6
B. Bayer Moved To Strike the Supplemental Couceyro Report Only After Learning That the Test Data Refute Dr. Moore's Conclusions	8
C. Biogen's Clone 4 Experiment Was Attorney Work Product Until Biogen Determined To Rely on It	9
D. Biogen Served the Supplemental Couceyro Report To Maximize Bayer's Ability To Prepare To Take His Deposition	10
II. Bayer Will Not Suffer Prejudice from the Supplemental Couceyro Report and the Case Schedule Will Remain Intact.....	11
A. Biogen Will Provide Bayer with the Discoverable Additional Materials It Requested	11
B. Bayer Cannot Complain About Discovery from Lofstrand Laboratories When Bayer Refused Biogen the Same Discovery.....	12
C. The Existing Case Schedule Adequately Protects Bayer and the Search for Truth.....	13
CONCLUSION.....	15

TABLE OF AUTHORITIES

	Page(s)
<u>Cases</u>	
<i>In re Paoli R.R. Yard PCB Litig.</i> , 35 F.3d 717 (3d Cir. 1994).....	5
<i>Meyers v. Pennypack Woods Home Ownership Ass'n</i> , 59 F.2d 894 (3d Cir. 1977).....	5, 6
<i>Reckitt Benckiser Inc. v. Tris Pharma, Inc.</i> , C.A. No. 09-3125 (FLW), 2011 WL 6722707 (D.N.J. Dec. 20, 2011).....	5

Bayer Healthcare Inc.’s Motion To Strike the Supplemental Rebuttal Expert Report of Dr. Pastor Couceyro (D.I. 486) recapitulates the issue already addressed in Biogen MA Inc.’s December 13 and 23 letters (D.I. 479, 485) and Bayer’s December 13 letter (D.I. 482). Biogen nevertheless respectfully submits this memorandum of law in opposition to Bayer’s motion.

INTRODUCTION

Bayer’s July 29 expert report from Dr. Gordon Moore injected into the case what Bayer describes as a show-stopper: that Bayer’s tests of a piece of DNA called “Clone 4” prove that an earlier Biogen patent supposedly anticipates, and thus invalidates, Claim 1 of the ’755 Patent. As the Court knows, Biogen contends that Bayer should have disclosed this invalidity theory far earlier, and Biogen thus moved to strike the Moore Report as untimely. Bayer resisted, stressing that the Clone 4 issue should be resolved on the merits, not on the timeliness of disclosure. Now that Biogen has completed its own testing and confirmed that Dr. Moore’s work was shoddy and that Clone 4 does not meet the requirements of the ’755 Patent, however, Bayer has changed its tune. It now seeks to preclude Biogen’s testing as untimely. And, perhaps because the cases use the words “bad faith,” Bayer accuses Biogen’s counsel of all manner of dishonesty.

The invective is as regrettable as it is wrong. Biogen has worked diligently

to put itself on equal footing with Bayer, by securing the testing data and analysis needed to respond to Dr. Moore's assertions regarding Clone 4 on the merits. Those data and that analysis are now set forth in the Supplemental Rebuttal Expert Report of Biogen's expert Dr. Pastor Couceyro ("the Supplemental Couceyro Report"). The Court should not strike that report, but should instead permit the parties to move forward now to address these issues on the merits, the very resolution Bayer wanted when it thought that surprise had given it the upper hand. (*See* D.I. 460 at 12.)

To be clear, Biogen could not have disclosed its own test results prior to the rebuttal-expert-report deadline. Biogen did not know there was an issue regarding Clone 4—indeed, Biogen did not even know Clone 4 existed—until it received Dr. Moore's July 29 report. Conducting properly designed hybridization experiments with the necessary redundancies and controls—steps that Dr. Moore himself omitted—takes months. First and foremost is the difficulty of finding a laboratory capable of conducting such tests using radioactive materials, then there is the time to design the experiments, obtain the necessary reagents and samples, and develop the experimental protocol, all of which must be done before any experiment can be performed. In addition, while each experiment only takes a matter of weeks, robust testing requires that the experiments be replicated to guard

against anomalous results.

Imperiled by Bayer’s delay in disclosing Clone 4 and Bayer’s four-year head start, Biogen proceeded with both options available to it: it moved to strike the Moore Report, and it sought a laboratory that could, as quickly as possible, do the appropriate testing. Having not received testing data in time to include it, Biogen served Dr. Couceyro’s initial rebuttal report on the rebuttal-expert-report deadline, addressing all of the issues it was then able to address.

On December 6, when the tests commissioned by Biogen had been preliminarily completed, Biogen contacted Bayer to discuss whether Bayer would consent to the service of a supplemental rebuttal report from Dr. Couceyro. Biogen proposed that service of such a report could moot Biogen’s motion to strike the Moore Report, an outcome that appeared preferable to the Court at oral argument. Bayer asked whether Biogen had conducted its own testing, and Biogen confirmed that it had done so. Bayer sought Biogen’s testing protocol, which Biogen provided.

On December 12—after it had received and reviewed Biogen’s testing protocol—Bayer announced it would object to a supplemental report, citing unspecified timing concerns. Bayer said nothing about “bad faith” by Biogen. The next day, Biogen wrote to update the Court regarding the parties’ efforts to resolve

Biogen's motion to strike, and offered to withdraw that motion in exchange for leave to serve a supplemental expert report.

Apparently unsatisfied with the parties' pending letters on this subject, Bayer has now filed this motion. The core of its argument is that Biogen delayed conducting its own experiments so that it would get results only in December. That is simply wrong. No rational litigant would prefer a motion to strike an adversary's expert report over responding on the merits. It was not a surprise when the Court expressed a preference that the parties find some solution that would allow Biogen to withdraw its motion to strike the Moore Report. At the time of oral argument, however, Biogen did not know whether such a solution would be possible. Testing was underway, but the test results were incomplete, and had they turned out to be inconclusive or otherwise unreliable then Biogen would have sought to press its motion to strike. As it happened, the laboratory that Biogen ultimately found was able to get the tests done as quickly as possible, and the results are scientifically valid. That Bayer does not like the results—they show that Dr. Moore is wrong—is not a basis to preclude their use at trial.

This is core rebuttal expert work. Bayer took four years to unveil a theory on July 29. Biogen took less than four months to respond to it. The parties now can, and should, conduct expert discovery. (To that end, Biogen has offered Dr.

Couceyro for deposition on January 6; Bayer has not yet responded whether it will take his deposition on that day even on issues unrelated to Biogen's testing. The deposition will, however, be scheduled eventually.) The Court should deny Bayer's motion, permit Biogen to serve the Supplemental Couceyro Report, and thus allow Biogen to withdraw its motion to strike the Moore Report.

ARGUMENT

The Third Circuit identified factors to be weighed in deciding whether to preclude evidence in *Meyers v. Pennypack Woods Home Ownership Ass'n*, 59 F.2d 894, 904–905 (3d Cir. 1977). Judge Wolfson's decision in *Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, C.A. No. 09-3125 (FLW), 2011 WL 6722707 (D.N.J. Dec. 20, 2011), sets forth how the *Pennypack* factors should be applied in deciding a motion to strike an expert report for failure to make discovery:

It is well established that a court has discretion to exclude evidence for a party's failure to adhere to the schedule set by the court. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791 (3d Cir. 1994). The Third Circuit has established four factors that a court should balance before precluding evidence. *Meyers*, 559 F.2d 894. Along with the importance of the excluded testimony, the *Pennypack* factors include: (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or other cases in the court; and (4) bad faith or willfulness in failing to comply with the court's order. *Id.* at 904–05.

Reckitt Benckiser, 2011 WL 6722707, at *6.

The *Pennypack* factors weigh against granting Bayer’s motion to strike. In that regard, the Court should be clear about what is at stake here: Bayer believes that its tests and Dr. Moore’s opinions about Clone 4 are case-dispositive. Bayer asks the Court to deny Biogen’s motion to strike the Moore Report, and also to preclude Biogen from offering its own tests in response. Then, Bayer says, it will move for summary judgment on the lopsided evidentiary field it created.

To be clear, in view of the emphatic declaration from Bayer’s counsel that Clone 4 “is not in the prior art” to the ’755 Patent (Nov. 22, 2016 Tr. at 110:9–15), Biogen believes Bayer’s anticipation argument is fatally flawed. But Bayer takes a different view, and the prior art status of Clone 4 is no reason to give Bayer the upper hand with regard to test results. Bayer delayed until July 29 revealing its Clone 4 experiments. Biogen wants only to now be on equal footing with Bayer, either by providing its own testing in response or by the Court striking the Moore Report. The Court made clear it prefers an equitable outcome other than striking that report. Frankly, so does Biogen. But Bayer’s approach—that Bayer’s test results and opinion testimony stand unrebutted—is inequitable and unnecessary.

I. Biogen Acted Diligently To Obtain Equal Footing with Bayer

A. Biogen Sought To Conduct the Necessary Experiments Quickly

After Bayer served the Moore Report, Biogen sought a laboratory to conduct

its own Clone 4 experiments. (*See* D.I. 479 at 2.) The search was complicated by the need to replicate Bayer's own testing; Bayer used radioactive labeling materials in its tests, and few facilities are certified to handle that material. Dr. Moore himself acknowledges this obstacle in his report. (D.I. 457-2, Ex. A at ¶ 56 (“[C]omparatively few contract laboratories [that] remain equipped” for radioactive DNA labeling.”).)

Biogen's first attempt to find a laboratory was a time-consuming dead end. The first laboratory that Biogen retained, Charles River, initially said they could do the testing, but would need several months. (*See* Nov. 22, 2016 Tr. at 123:19–124:15; D.I. 479 at 2–3.) Then, however, Charles River said it could not conduct the testing at all, because the tests violated their Good Laboratory Practice Protocol.

Biogen then found another, properly-certified laboratory, Lofstrand Laboratories, to perform the experiments on an expedited basis. Those tests began on November 3, 2016, but Biogen did not receive the final results until Friday, December 9. Even before that, on December 6, Biogen informed Bayer's counsel that tests were being conducted and would be the subject of the proposed supplemental rebuttal report from Dr. Couceyro. Thereafter, Biogen worked diligently with Dr. Couceyro and provided the Supplemental Couceyro Report to

Bayer on December 20.

B. Bayer Moved To Strike the Supplemental Couceyro Report Only After Learning That the Test Data Refute Dr. Moore's Conclusions

At the November 22 hearing, the Court requested that Biogen and Bayer try to resolve Biogen's pending motion to strike Dr. Moore's expert report. The next day, counsel for Biogen and Bayer conferred, and Biogen indicated that it may wish to serve a supplemental report as part of a resolution. While the parties did not reach an agreement, counsel for Bayer did not object to the idea of a supplemental rebuttal report from Dr. Couceyro.

As noted above, Biogen actually reached out to Bayer again before Biogen even had the final test data in hand. On December 6, once Biogen learned that it likely would receive meaningful test data, Biogen made the following proposal to Bayer:

- (1) Bayer would stipulate that Clone 4 "is not in the prior art" to the '755 Patent. (*See* Nov. 22, 2016 Tr. at 110:11–17.)
- (2) By December 20, 2016, Biogen would serve a supplemental rebuttal expert report from Dr. Couceyro responding to the Moore Report.
- (3) Biogen would produce Dr. Couceyro for deposition before the close of expert discovery on January 13, 2017.
- (4) Biogen would withdraw its motion to strike the Moore Report.

(D.I. 472 at 1–2.)

Bayer rejected that proposal. Its only basis was unspecified timing concerns.

It offered no proposal of its own. And as soon as Bayer saw that Biogen's test data refute Dr. Moore's Clone 4 theory, Bayer brought this motion to strike, abandoning its much-trumpeted desire to have the Clone 4 issue resolved on the merits.

C. Biogen's Clone 4 Experiment Was Attorney Work Product Until Biogen Determined To Rely on It

Bayer's motion assumes that Biogen should have disclosed, in November, that Biogen was seeking to conduct its own testing. Not so. As Bayer itself argued when it opposed Biogen's motion to strike the Moore Report, “[s]cientific testing conducted for the purpose of litigation is protected work product until a party chooses to disclose and rely on it.” (D.I. 460 at 7.)

When Biogen sought to hire a laboratory, and then another laboratory, to conduct testing in response to the Moore Report, Biogen had no idea whether it would be able to find such a laboratory or to obtain meaningful test data. When the parties were before the Court in November, the testing was not yet complete. Indeed, one of Dr. Moore's failings is that he chose not to repeat the lone test performed by Marin Biologic to verify the purported results. Dr. Moore relies on a single test, even though it is well known in science that a single test may be erroneous and thus tests should be repeated to ensure the result is reliable. Biogen did not wish to repeat Dr. Moore's mistake, and thus needed not only to test, but to re-test. Unless and until Biogen had final results in hand, the existence of ongoing

efforts was work product.

Perhaps because it knows this, Bayer accuses Biogen of falsely saying it would cease all efforts to test Clone 4. That never happened. The reason that Biogen returned Bayer's Clone 4 samples is that Bayer asked for them back. The reason that Biogen moved to strike the Moore Report is that striking that report would be another way to put Biogen on equal footing with Bayer. And the reason that Biogen took Dr. Moore's deposition on November 11 was that Bayer offered that date. There was no campaign of subterfuge, no dishonesty, and no bad faith in any of this conduct, or any conduct by Biogen.

D. Biogen Served the Supplemental Couceyro Report To Maximize Bayer's Ability To Prepare To Take His Deposition

Bayer also complains that by serving the Supplemental Couceyro Report on December 20, Biogen sought to "arrogate[] to itself the power to adjust the Court's Scheduling Order." (D.I. 486-5 at 5.) Not so. Biogen provided that report by the deadline it had proposed in its own offer to compromise, so that Bayer would not complain that (a) Biogen had abandoned its own proposal, or (b) Biogen delayed sending a report after it was complete, or (c) it was unable to timely prepare to depose Dr. Couceyro. As it turns out, Bayer still managed to complain about its ability to prepare for depositions. Consider, however, how much more vociferously Bayer would be complaining if Biogen had withheld the

Supplemental Couceyro Report.

Nor should Bayer be heard to complain here anyway. The night before the deposition of Dr. Moore, Bayer served a supplemental Moore Rebuttal Report that it called a “Correction” report. Balcof Decl., Ex. A (Nov. 10, 2016 E-Mail Correspondence from S. Bowers to Counsel) at 1. Bayer did not seek leave from the Court, or ask Biogen whether it would consent to the service of the report, or even provide Biogen with advanced notice that it should expect service. Biogen took Dr. Moore’s deposition the next day, as scheduled. Thus, Bayer’s current complaints that Biogen has “arrogated to itself” the right to serve a supplemental report ring hollow—Biogen has simply tried to ensure that the current schedule will not be compromised.

II. Bayer Will Not Suffer Prejudice from the Supplemental Couceyro Report and the Case Schedule Will Remain Intact

A. Biogen Will Provide Bayer with the Discoverable Additional Materials It Requested

On December 23, Bayer has requested a number of additional materials relating to the experiments conducted by Lofstrand Laboratories. (*See* D.I. 486-4.) Biogen agreed to produce it, subject to the attorney-work-product doctrine. *See* Balcof Decl., Ex. B (Dec. 29, 2016 E-Mail Correspondence from Counsel for Biogen to Counsel for Bayer) at 1–2. Thus:

- Biogen will send Bayer the requested DNA material at an address of Bayer's choosing.
- To Biogen's knowledge, it has already provided all images of autoradiographs, gels, or other experimental results created by Lofstrand or Dr. Couceyro. *Id.* at 2.
- Biogen has undertaken to provide high resolution scans of the x-ray films provided by Lofstrand—a courtesy that Bayer did not extend Biogen. *Id.*
- Biogen already provided Bayer the requested experimental protocol followed by Lofstrand as an attachment to the Supplemental Couceyro Report. *Id.*
- Biogen will make the original autoradiographs and notebooks available for inspection in Washington D.C. or New York.

B. Bayer Cannot Complain About Discovery from Lofstrand Laboratories When Bayer Refused Biogen the Same Discovery

One of the consequences of Bayer's untimely disclosure of its Clone 4 contention was that Biogen could not obtain fact discovery from Marin Biologic, the laboratory that conducted Bayer's Clone 4 tests. (*See, e.g.*, D.I. 457-1 at 13.) Bayer argued that this was harmless because Bayer disclosed the information supporting Dr. Moore's opinions and because Dr. Moore would be deposed. (*See* D.I. 460 at 13.)

Here, too, Bayer has had a change of heart. It claims prejudice from being denied the chance to take discovery of Lofstrand Laboratories. (*See* D.I. 486-5 at 17-18.) But Biogen met the standard Bayer itself laid down: Bayer has or will

soon have all materials supporting Dr. Couceyro's opinions, and will be able to depose him.

Bayer contends that it is important that Dr. Couceyro was not present during the experiments at Lofstrand Laboratories. It is not important; Dr. Couceyro reviewed the testing protocol, Lofstrand's notes, and the final results. For that matter, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] See, e.g., Balcof Decl., Ex. C (November 11 Moore Dep. Tr.) at 13:10–14:9; 18:10–15; 21:1–24; 44:17–45:2; 46:4–7; 93:2–95:6; 169:12–170:13; 186:2–10. But if it were somehow important, Bayer could surely elicit from Dr. Couceyro the (undisputed) fact that Dr. Couceyro was not there when the tests were performed.

C. The Existing Case Schedule Adequately Protects Bayer and the Search for Truth

The Couceyro Deposition. Dr. Couceyro is currently scheduled to be deposed on January 6, although it remains to be seen whether Bayer's counsel will actually come to the deposition. Instead of preparing for that deposition—or, more likely, given the size of its legal team, at the same time as it prepared for that deposition—Bayer filed this motion. After only three days with the Supplemental Couceyro Report, Bayer had already dug in on the merits and identified what it

characterizes as “deep flaws” in the Biogen testing. The experiments that Biogen conducted are similar to those that Bayer itself conducted, and the ways in which they differ—for example, being repeated three times—are precisely those that Biogen identified back in September as having been the flaws in Bayer’s tests. There is no surprise here. And there is no impediment to Bayer’s deposing Dr. Couceyro on January 6. If Bayer wants a later date, though, Biogen has offered and remains willing to find an agreeable later date.

Summary Judgment. The Supplemental Couceyro Report should have no impact on Bayer’s ability to file its theoretical summary judgment motion. As indicated above, Biogen is prepared to send Bayer its DNA material immediately. In light of Bayer’s claim that the hybridization tests can be completed in one to two weeks (Nov. 22, 2016 Tr. at 110:4–7; 127:4–6), Bayer has more than enough time to conduct additional testing before its opening summary judgment briefs are due. Moreover, Bayer’s own motion will rest, one assumes, on Dr. Moore’s tests, which Bayer has had for years. Biogen will likely oppose that motion based on Dr. Couceyro’s opinions. Bayer’s reply brief is not due until March 31.

Trial. Trial is nine months away. Aside from the incorrect *ipse dixit* that trial would need to move if the summary-judgment schedule moves, Bayer offers no explanation for how one expert out of thirty or more experts could imperil a

trial that is months and months away. There is no such peril.

CONCLUSION

For the reasons set forth above, the Court should deny Bayer's Motion to Strike the Supplemental Couceyro Report.

Dated: December 30, 2016
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